U.S. FOOD & DRUG ADMINISTRATION

August 5, 2020

To: Manufacturers of Surgical Masks;
Health Care Personnel;
Hospital Purchasing Departments;
Authorized Distributors and Authorized Importers; and
Any Other Stakeholders

The U.S. Food and Drug Administration (FDA) is issuing this Emergency Use Authorization (EUA) in response to concerns relating to the insufficient supply and availability of disposable, single-use surgical masks[1,2] (hereafter also referred to as "surgical masks") for use in healthcare settings by health care personnel (HCP)[3] as personal protective equipment (PPE)[4] to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[5]

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[1] A surgical mask is a mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks are generally regulated by FDA as Class II devices under 21 CFR 878.4040 – Surgical apparel.

[2] FDA-cleared surgical face masks, non-surgical face masks, surgical masks with antimicrobial/antiviral agent, and all particulate filtering facepiece respirators are not within the scope of this authorization.

[3] For the purposes of this EUA, HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

[4] Surgical masks may be effective in blocking splashes and large particle droplets. While surgical masks are not protective against smaller airborne particulates as described in Section II, they are considered PPE because they are intended to be used to protect HCP from infectious disease hazards. Surgical masks are different from non-surgical face masks, which are only used as source control by the general public and are not considered PPE.

[5] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[6]

As discussed further below, I have concluded that a surgical mask meeting the criteria set forth in Section II meets the criteria for issuance of an EUA under Section 564(c) of the Act.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of surgical masks that meet the criteria set forth in Section II pursuant to the Conditions of Authorization (Section IV) of this letter (referred to in this letter as "authorized surgical masks"). Authorized surgical masks will be added to this letter of authorization in Appendix A, as described in the Scope of Authorization (Section II).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of authorized surgical masks as described in the Scope of Authorization (Section II) of this letter for use in healthcare settings by HCP as PPE during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized surgical masks may be effective for use in healthcare settings by HCPs as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic, and that the known and potential benefits of the authorized surgical masks, when used consistent with the scope of this authorization (Section II), outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of these authorized surgical masks for use in healthcare settings by HCP to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.[7,8]

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[6] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

[7] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[8] There are not sufficient quantities of surgical masks to meet the needs of the U.S. healthcare system. These articles of PPE are an integral part of patient care during the COVID-19 pandemic. Providing authorization for the introduction into interstate commerce of surgical masks by manufacturers, including those that do not customarily engage in the manufacture of medical devices, helps meet the needs of the healthcare system. Providing HCP who

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized surgical masks, for use in healthcare settings by HCP as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.

Surgical masks are not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators. Surgical masks may be effective in blocking splashes and large-particle droplets; however, because of the loose fit between the surface of the surgical mask and the user's face, leakage can occur around the edge of the mask when the user inhales. Therefore, a surgical mask may not provide the user with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection. For this reason, surgical masks are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure. In such clinical conditions, a filtering facepiece respirator (such as an N95 respirator) with a tight fit is recommended to provide a more reliable level of respiratory protection against pathogenic biologic airborne particulates.

Authorized Surgical Masks

Surgical masks that have been designed, evaluated, and validated consistent with the following performance criteria and that are not excluded, are authorized for the above-described intended use. The following surgical masks are excluded from the scope and are not authorized under this EUA: (1) surgical masks that are FDA-cleared; (2) surgical masks that are manufactured in China; and (3) surgical masks that include drugs, biologics, nanoparticles, or antimicrobial/antiviral agents. A surgical mask that is not excluded is authorized if it meets the following performance criteria:

- Fluid resistance requirements (liquid barrier performance) consistent with ASTM F1862: *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);* [9]
- Flammability performance consistent with the definition of either a Class 1 or Class 2 textile in 16 CFR Part 1610;

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are on the forefront of the COVID-19 response with sufficient PPE is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

[9] For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

- Particulate filtration efficiency requirements consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks*;
- Air flow resistance (i.e., breathability) requirements with an acceptance criterion of <6 mm H_2O/cm^2 for differential pressure (delta P) testing consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks* for those masks composed of 4 or more layers; and
- The materials of manufacture are either (1) non-cytotoxic, non-irritating and non-sensitizing consistent with the recommendations in FDA's guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'"[10] or (2) conform to the following biocompatibility standards:
    - ISO 10993-1: *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
    - ISO 10993-5: *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
    - ISO 10993-10: *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.*

To be added to Appendix A as an authorized surgical mask under this EUA, the surgical mask must not be excluded and manufacturers must provide test reports that demonstrate that the surgical mask meets the performance criteria above. Manufacturers may request the inclusion of any surgical mask model in Appendix A by submitting a request to FDA with the subject line "Surgical Masks EUA" to CDRH-nondiagnosticEUA-templates@fda.hhs.gov and include the following information, which will allow FDA to confirm that the surgical mask meets the criteria and provide other relevant information:

- Manufacturer contact information, name and address of business, email address, contact information for a U.S. agent (if any), in addition to general information about the device such as the proprietary or brand name, model number (if any);

- A copy of the product labeling;

- An estimate of the number of surgical masks you are planning to market and distribute during the public health emergency;

- A summary of the evidence demonstrating that the surgical mask meets the above criteria, including test reports; and

- A list of authorized distributor(s) and/or authorized importer(s),[11] including contact information (name, address, contact person, phone number, and email).

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[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and.

[11] "Authorized Distributor(s)" and "Authorized Importer(s)" are identified by the manufacturer in an EUA submission as an entity allowed to import and/or distribute the device. If the entity distributing the device is also the entity importing the device, the manufacturer should so indicate on the list provided to FDA.

The labeling of the authorized surgical masks must:

- Describe the product as a disposable, single-use surgical mask. The labeling must include a list of the body contacting materials (which does not include any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents);

- State that the product is not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators;

- State that surgical masks are not intended to provide protection against pathogenic biological airborne particulates and are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure; and

- Not include statements that would misrepresent the product or create an undue risk in light of the public health emergency. For example, the labeling must not include any express or implied claims for: (1) reuse, (2) antimicrobial or antiviral protection or related uses, (3) infection prevention, infection reduction, or related uses, or (4) viral filtration efficiency.

Authorized products must be accompanied by the above required labeling, and in addition, the authorized products must be accompanied by the following information pertaining to the emergency use, which are authorized to be made available to HCPs:

- Fact Sheet for Healthcare Personnel: Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic

The manufacturer's labeling (which must meet the labeling requirements specified above) and the fact sheet, are referred to as "authorized labeling."

FDA may remove an authorized surgical mask from Appendix A of this EUA if FDA has reason to believe that the product no longer meets the Scope of Authorization (Section II) or any of the Conditions of Authorization (Section IV). FDA will provide the manufacturer 24 hours advance notice of such removal and may work with the manufacturer to resolve the issue(s) that led to removal of the device(s) from Appendix A. Products that are removed from Appendix A will appear on a list maintained on FDA's website.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized surgical masks as described within this section (the Scope of Authorization, Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that authorized surgical masks may be effective as described within this section (the Scope of Authorization, Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that authorized surgical masks (as described in the Scope of Authorization, Section II), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of authorized surgical masks must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), surgical masks that are determined to meet the criteria set forth in this section (Section II) are authorized under the terms and conditions of this EUA.

III. Waiver of Certain FDA Requirements

I am waiving applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized surgical masks that are used in accordance with this EUA.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions to this authorization:

Manufacturers of Authorized Products

A. Manufacturers will make authorized products available with the authorized labeling (including the labeling requirements described in Section II). Manufacturers must make available all labeling in English, to each end user facility (e.g., each hospital) that receives the authorized products, and may include the authorized labeling with each individual authorized product.

B. Manufacturers must comply with 21 CFR Part 803, and must have a process in place for reporting adverse events of which they become aware to FDA consistent with 21 CFR Part 803. See FDA's webpage "Medical Device Reporting (MDR): How to Report Medical Device Problems"[12] for additional information concerning reporting requirements under 21 CFR Part 803 and procedures.

C. Manufacturers will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[12] FDA guidance, titled "Medical Device Reporting (MDR): How to Report Medical Device Problems" is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

D. Through a process of inventory control, manufacturers will maintain records of the entities to which they distribute the surgical masks and the numbers of each such product they distribute.

E. Manufacturers will notify FDA of any authorized distributor(s) and/or authorized importers of the authorized surgical masks, including the name, address, and phone number of any authorized distributor(s) and authorized importer(s), and provide authorized distributor(s) and authorized importer(s) with a copy of this EUA and any updates.

F. Manufacturers are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

G. Manufacturers of authorized surgical masks will submit, upon FDA's request, new lots of the authorized surgical masks for testing by FDA or by another entity designated by FDA. The manufacturers must not distribute any lot or shipment that fails testing, meaning the lot or shipment containing a lot that did not perform as expected based on the performance criteria in the Scope of Authorization (Section II). FDA will make the manufacturer aware of the testing results.

Authorized Distributors and Authorized Importers

H. Authorized Distributors and Authorized Importers must ensure that authorized surgical masks comply with condition A of this EUA.

I. Through a process of inventory control, Authorized Distributors and Authorized Importers will maintain records of the entities to which they distribute the surgical masks and how many of each authorized product model they distribute or import, as applicable.

J. Authorized Distributors and Authorized Importers will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

K. Authorized Distributors and Authorized Importers of authorized surgical masks will submit, upon FDA's request, lots or shipments of the authorized surgical masks for testing by FDA or by another entity designated by FDA. Authorized Distributors and Authorized Importers must not distribute any lot or shipment that fails testing, meaning the lot or shipment containing a lot that did not perform as expected based on the performance criteria in the Scope of Authorization (Section II). FDA will make the Authorized Distributor or Authorized Importer aware of the testing results.

Conditions Related to Advertising and Promotion

L. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized surgical mask shall be consistent with the labeling requirements listed in Section II and this section (Conditions of Authorization) of this EUA, and the applicable requirements set forth in the Act and FDA regulations.

M. No descriptive printed matter, including advertising or promotional materials, relating to the use of the authorized surgical mask may represent or suggest that such product is safe or effective for the prevention or treatment of COVID-19.

N. All descriptive printed matter, including advertising and promotional materials, relating to the use of the product shall clearly and conspicuously state that:

- The product has not been FDA cleared or approved.
- The product has been authorized by FDA under an EUA for use in healthcare settings by HCP as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.
- This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration